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(54) Title: METHOD AND INSTRUMENTATION FOR POSTERIOR INTERBODY FUSION			
(57) Abstract.			
<p>A method and instrumentation for spinal interbody fusion is disclosed. The instruments and methods are particularly adapted for interbody fusion from a posterior approach to the spine. One instrument is a retractor (10) having a lockable pivotally mounted handle (12). Another instrument is a template (100) for straddling the dura. A modular distractor (150) is also provided and preferably includes a tapered shaft (160) with a visualization window (168) disposed therein. Yet another instrument is a depth gauge (360) to verify bone opening depth and dimension, preferably including a radiopaque portion (370). A method contemplates the use of these instruments to prepare a disc space to receive an implant.</p>			

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METHOD AND INSTRUMENTATION FOR POSTERIOR INTERBODY FUSION

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BACKGROUND OF THE INVENTION

The present invention relates generally to surgical procedures for spinal
10 stabilization and more specifically to instrumentation and techniques for inserting a
spinal implant within the intervertebral disc space between adjacent vertebra.
More particularly, while aspects of the present invention may have other
applications, the invention provides instruments and techniques especially suited
for interbody fusion from a generally posterior approach to the spine

15 Various surgical methods have been devised for the implantation of fusion
devices into the disc space. Both anterior and posterior surgical approaches have
been used for interbody fusions. In 1956, Ralph Cloward developed a method and
instrumentation for anterior spinal interbody fusion of the cervical spine. Cloward
surgically removed the disc material and placed a tubular drill guide with a large
20 foot plate and prongs over an alignment rod and then embedded the prongs into
adjacent vertebrae. The drill guide served to maintain the alignment of the
vertebrae and facilitated the reaming out of bone material adjacent the disc space.
The reaming process created a bore to accommodate a bone dowel implant. The
drill guide was thereafter removed following the reaming process to allow for the
25 passage of the bone dowel which had an outer diameter significantly larger than
the reamed bore and the inner diameter of the drill guide. The removal of the drill
guide left the dowel insertion phase completely unprotected. Thus, Cloward's
method and instrumentation was designed for and limited to an anterior surgical
approach and was inappropriate for a posterior application.

30 Furthermore, B.R. Wilterberger described in a paper entitled "Dowel
Intervertebral Fusion as Used in Lumbar Disc Surgery" (published in *The Journal
of Bone and Joint Surgery*, volume 39A, pgs. 234-92, 1957), the unprotected
drilling of a hole from a posterior approach into the lumbar spine between the
nerve roots and across the disc space, and then inserting a bone dowel into that disc

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space. While Wilterberger had taken the Cloward concept of circular drilling followed by dowel fusion and applied it to the lumbar spine from a posterior approach, he had not further improved the method, nor had he advanced the instrumentation to provide adequate protection for the sensitive vessels and neurological structures adjacent to the operating field.

U.S. Patent No. 5,484,437 to Michelson discloses a technique and associated instrumentation for inserting a fusion device from a posterior surgical approach that provides greater protection for the surrounding tissues and neurological structures during the procedure. As described in more detail in the '437 patent, the surgical technique involves the use of a distractor having a penetrating portion that urges the vertebral bodies apart to facilitate the introduction of the necessary surgical instrumentation. The '437 patent also discloses a hollow sleeve having teeth at one end that are driven into the vertebrae adjacent the disc space created by the distractor. These teeth engage the vertebra to maintain the disc space height during subsequent steps of the procedure following removal of the distractor. In accordance with one aspect of the '437 patent, a drill is passed through the hollow sleeve to remove portions of the disc material and vertebral bone to produce a prepared bore for insertion of the fusion device. The drill is then removed from the sleeve and the fusion device is positioned within the disc space using an insertion tool.

While the more recent techniques and instrumentation represent an advance over earlier surgical procedures for the preparation of the disc space and insertion of the fusion device, the need for improvement still remains. The present invention is directed to this need and provides convenient methods and instruments to insure safe and effective preparation of a disc space in conjunction with implant placement.

SUMMARY OF THE INVENTION

One object of the present invention is to provide an improved retractor assembly permitting variable placement of the handle with respect to a retractor blade. The retractor comprises a retractor blade, a shaft having a first portion connected to the retractor blade, and an opposite second portion pivotally connected to a handle. Preferably, the assembly further includes a locking mechanism selectively locking the handle to the second portion to limit pivotal movement of the handle in relation to the shaft.

In another aspect of the present invention, a method of dura retraction is provided for posterior access to the spine. The method comprises providing a retractor having a retractor blade pivotally connected to a handle, and the handle having a locking mechanism to selectively lock the handle to the retractor. A portion of the dura is exposed and the retractor is inserted with the handle in an insertion position and the locking mechanism in a locked position. The dura is then retracted to expose underlying spinal elements. Preferably, the locking mechanism is unlocked to allow the handle to pivot in relation to the retractor blade. In this aspect, the handle is pivoted to a holding position and locked to maintain the handle in the locked position.

Yet a further aspect of the present invention is a template for straddling the dura in a spinal surgery to facilitate marking a surgical site to gain access to the disc space in preparation for implant placement. The template comprises a body having an upper surface and a lower surface facing the dura, and an opening formed between the upper surface and the lower surface. A shaft having a first end and a second end is connected to the body and extends away from the upper surface. Preferably, a working tube is connected to the body in substantial alignment with the opening and extends from the lower surface, the tube having a first diameter. A locator extension engages the body and is spaced from the tube to provide a space for passage of the dura therebetween. The locator extension extends from the lower surface and has a second diameter that is less than the tube

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diameter. Optionally, the body may be formed to match the maximum area of the insertion instrumentation at the engagement with the vertebral bodies, thereby allowing marking of the bone needing removal.

Still a further object of the present invention is to provide a spinal disc
5 space distractor assembly. Preferably, the distractor includes a tapered shaft portion. Optionally, a window may be formed through the shaft for visualization. In one form of the invention, the assembly comprises a driving portion removably coupled to a distractor tip. The driving portion is coupled to transmit rotational and longitudinal forces. Preferably the assembly includes an outer shaft having a
10 first driving shoulder for transmitting rotational force end and an opposite second driving shoulder for receiving a rotational force. An inner shaft is slidably disposed within at least a portion of the outer shaft, the inner shaft having a first connection end and an opposite second connection end. The first connection end is disposed adjacent the first driving shoulder. The assembly further includes a
15 distraction tip, the tip having a driving surface adapted for engagement with the first driving shoulder and a connection surface adapted for engagement with the first connection end. A handle interconnects the inner and outer shafts and maintains the tip in contact with the outer shaft. In one embodiment the outer shaft is tapered to provide greater visualization. Further, the outer shaft may have a
20 visualization window extending there through.

It is yet a further object to provide an instrument for determining the depth and size of an opening formed between two adjacent vertebral bodies. The instrument comprises an elongated shaft and preferably a radiolucent tip attached to the shaft, the tip including at least one radiopaque marker. Preferably, the
25 instrument includes a distal tip sized to match the diameter or shape of the opening intending to be created.

The present invention also contemplates a method of preparing a disc space and inserting an implant. The method utilizes one or more of the instruments described above to prepare the disc space for receiving an implant.

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Related objects and advantages of the present invention will be apparent from the following description.

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BRIEF DESCRIPTION OF THE DRAWINGS

- Fig. 1 (a) is a perspective view of a retractor according to the present invention.
Fig. 1(b) is a partial cross-sectional side view of the retractor of Fig. 1.
5 Fig. 2(a) is an end view of a shaft of a portion of the retractor of Fig. 1.
Fig. 2(b) is a side view of the retractor shaft of Fig. 1.
Fig. 3(a) is a side view of the handle of Fig. 1.
Fig. 3(b) is a bottom view of the handle of Fig. 3(a).
Fig. 4(a) is a perspective view of an intraoperative template according to
10 another aspect of the present invention.
Fig. 4(b) is a partial cross-sectional side view of the intraoperative template of
Fig. 4(a).
Fig. 5 is a perspective view of a further embodiment of an intraoperative
template according to the present invention.
15 Fig. 6 is a perspective view of still a further embodiment of an intraoperative
template according to the present invention.
Fig. 7 is perspective view of the intraoperative template of Fig. 6 with handle
and trephine.
Fig. 8 is a perspective view of yet a further embodiment of an intraoperative
20 template according to the present invention.
Fig. 9 is a perspective view of still a further intraoperative template.
Fig. 10 is a cross-sectional view of the embodiment of Fig. 4(a).
Fig. 11 is a perspective view of a distractor according to the present invention.
Fig. 12(a) is an exploded perspective view of a modular distractor according to
25 the present invention.
Fig. 12(b) is a substantially assembled perspective view of the modular
distractor of Fig. 12(a).
Fig. 13 is a plan elevation of a fully assembled distractor of Fig. 12(b).
Figs. 14(a) through 14(c) are partial cross-sectional side views taken along line
30 14a-14a showing the modular distractor according to Fig. 13.

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Fig. 15 is a side elevational view of an outer sleeve according to the present invention.

Fig. 16 is a side view of the outer sleeve of Fig. 15 rotated 90° about the longitudinal axis.

5 Fig. 17 is a perspective view of the outer sleeve of Fig. 15 in combination with the distractor of Fig. 13.

Fig. 18 is a perspective view of a depth stop according to one aspect of the present invention.

Fig. 19(a) is a side-elevational view of the depth stop of Fig. 22.

10 Fig. 19(b) is a side view of the depth stop of Fig. 19(a) rotated 90° about its longitudinal axis.

Fig. 19(c) is a cross-sectional view of the depth stop of Fig. 19(b).

Fig. 20 is a side-elevational view of an alternative embodiment of a depth stop according to the present invention.

15 Fig. 21 is a perspective view of an outer sleeve in combination with a depth stop and reamer.

Fig. 22 is a perspective view of a depth gauge according to one aspect of the present invention.

20 Fig. 23 is a perspective view of the depth gauge of Fig. 22 in combination with an outer sleeve.

Fig. 24 is a perspective view of a tap in combination with an outer sleeve.

Fig. 25 is a perspective view of an implant inserter in accordance with another aspect of the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

For the purposes of promoting an understanding of the principles of the invention, reference will now be made to the embodiments illustrated in the drawings and specific language will be used to describe the same. It will nevertheless be understood that no limitation of the scope of the invention is thereby intended, such alterations and further modifications in the illustrated devices, and such further applications of the principles of the invention as illustrated therein being contemplated as would normally occur to one skilled in the art to which the invention relates.

The present invention relates generally to instruments and methods for performing vertebral interbody fusion. While it should be understood that the instruments disclosed herein may have many uses, it is particularly contemplated that they may be used to perform vertebral interbody fusion from a generally posterior approach to the spine. Such procedures typically involve the placement of dowels or other implants into the intervertebral disc space to promote fusion between adjacent vertebral bodies and to stabilization of the spine. Such implants may be formed of metal, ceramics, composites, bone or other bio-compatible materials, depending on the properties desired from the implant.

Referring now to Fig. 1(a), there is shown a retractor mechanism according to one aspect of the present invention. Retractor 10 includes a handle 12 pivotally connected to a shaft 14 having a distal end 17 connected to a retractor blade 16. While retractor blade 16 is shown as a semi-circular blade, it is contemplated that any of a variety of retractor blade shapes may be utilized in conjunction with handle 12 and shaft 14 of the present invention. Handle 12 is pivotable in relation to shaft 14 and may be releasably connected to shaft 14 adjacent enlarged end 18. As shown more clearly in Fig. 2, enlarged end 18 includes a series of grooves 24 on its upper surface 36. Handle 12 includes a locking mechanism 22 adapted to selectively engage annular groove 26 extending around enlarged end 18 of shaft 14, and at least one of grooves 24 disposed on the upper surface 36.

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Referring specifically to Fig. 1(b), locking mechanism 22 includes a flange 28 adapted for engaging a portion of annular groove 26 disposed on shaft 14. As shown in Fig. 3(b), flange 28 extends in a semi-circular fashion and includes substantially parallel straight extensions 31 and 33 positioned adjacent opening 35. Flange 28 defines an opening 35 for receiving a portion of the enlarged head 18 of shaft 14 to hold the shaft and handle in mating engagement. Locking mechanism 22 further includes an upper plate 34 having a downwardly extending internal projection 30 adapted to engage one of grooves 24 on shaft 14. Although only a single projection 30 is shown, it will be understood that multiple projections may be provided to engage one or more grooves on shaft 14. Disposed within handle 12 is an inner shaft 23 slidable within outer shaft 32 to at least partially close opening 35 to prevent passage of enlarged end 18 from the channel formed by flange 28. The position of inner shaft 23 is controlled by movement of thumb lever 20 sliding within slot 21 formed in outer shaft 32. Inner shaft 23 includes a projection 29 adapted to engage a portion of annular groove 26. Preferably, inner shaft 23 is biased to an extended position shown in Fig. 1(b) by spring 38 captured within outer shaft 32. In the extended position, inner shaft 23 retains handle 12 and shaft 14 in locked engagement.

In a locked position, flange 28 of locking mechanism 22 engages a semi-circular portion of annular groove 26 and projection 29 on inner shaft 23 also engages a further portion of annular groove 26. This engagement maintains handle 12 and shaft 14 securely engaged. To inhibit pivotal movement in the locked position, grooves 24 on enlarged end 18 are urged into engagement with projection 30 of locking mechanism 22, thereby positioning the projection in one of the grooves 24 to prevent rotation of handle 12 about the longitudinal axis of shaft 14. In an adjustment position, projection 29 may be partially withdrawn from annular groove 26 by movement of thumb lever 20 in the direction of arrow 25. With projection 29 in the adjustment position, there may be sufficient transverse movement of shaft 14 within opening 35 to disengage projection 30 from grooves 24 thereby permitting pivotal movement of handle 12 in relation to shaft 14 without complete removal of the handle. In the adjustment position, inner shaft 23 prevents movement of shaft 14

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entirely out of opening 35, thus maintaining the connection between handle 12 and shaft 14. With the locking mechanism in the adjustment position, the handle may be pivotally repositioned to a variety of positions. It will be understood that in a preferred embodiment, shaft 14 includes eight grooves 24, thereby permitting handle 12 to be locked in eight separate pivotal positions about shaft 14. Although eight grooves 24 are shown, it is contemplated that more or less grooves may be provided to accommodate various positions. Moreover, while grooves are shown on the top of shaft 14, it is contemplated that these may be placed around the exterior of enlarged head 18 to engage a projection correspondingly disposed in locking mechanism 22. Further, the placement of grooves and projections may be reversed such that the shaft includes one or more projections mating with grooves in the locking mechanism. Other mechanisms known to those skilled in the art for allowing selective pivotal movement between the shaft and handle are contemplated and come within the scope of the present invention.

In an unlocked position, projection 29 of inner shaft 23 is completely withdrawn from opening 35 by further movement of thumb lever 20 in the direction of arrow 25, thereby allowing enlarged end 18 to be removed from locking mechanism 22. The locking mechanism may also be placed in the unlocked position to insert a tool shaft.

Utilization of the above-described retractor device provides several advantages over retractors utilizing a fixed handle position. Specifically, in a first locked handle position, a surgeon may position the retractor device 10 to most effectively retract a desired neural structure or vessel. Once the surgeon has properly positioned the retractor adjacent the desired tissue and the tissue is retracted, handle locking mechanism 22 may be moved to the adjustment position and handle 12 pivoted about shaft 14 to a position for an assistant to maintain the tissue or vessel in the retracted position. Often, the assistant will be located on the opposite side of the patient from the surgeon and it is desirable that the handle be rotated out of the surgical field to provide the best access and visualization of the surgical site for the surgeon. Once properly positioned, the locking mechanism may be returned to the locked position to securely hold the handle and shaft in the selected arrangement. Further, handle 12

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may be removed from shaft 14 and utilized with a variety of instruments, such as those disclosed further herein. Use of a removable handle having the advantages described above may limit the total number of handles required for a surgical procedure or that must be supplied with a surgical set.

5 Referring now to Figs. 4 (a) and (b), there is shown an intraoperative template 40 according to another aspect of the present invention. Template 40 includes a shaft 42 interconnected with handle 44. Shaft 42 is centrally connected to the upper side of template body 48. Template body 48 defines a number of bone marking notches 50 around its perimeter and includes an integrally formed guide tube 46 extending from
10 its lower surface. Although an integrally formed guide tube is shown in a preferred embodiment, it will be understood that a removable guide tube may be connected adjacent an aperture in the body. Guide tube 46 defines a channel 47 to receive an instrument. Body 50 further defines an opening 49 adapted to receive a locator extension 51.

15 In Fig. 4(b) there is shown a partial cross-sectional view of the template of Fig. 4(a). Inserted within opening 49 is a removable locator extension 51 having a head 53. In a preferred embodiment locator extension 51 may be threadably received with opening 49 to prevent dislodgment. Diameter 41 of guide tube 46 is substantially larger than diameter 43 of locator extension 51. The additional space created by
20 utilization of a locator extension rather than a second guide tube sized to receive a cutting instrument limits the amount of compression that the dura 45 must undergo and increases the possibility that such a template may be utilized. Preferably, guide tube 46 and locator extension 51 are in substantially parallel alignment.

Referring now to Fig. 5, there is disclosed a second embodiment of an
25 intraoperative template according to the present invention. A second template 52 includes a handle 54 connected to a shaft 56 which is centrally connected to template body 58. Template body 58 further includes guide tube 60 and integrally formed post 62. A trephine 64 is illustrated extending into and through guide tube 60 with trephine cutting head 66 extending beyond distal end 61 of guide tube 60. The

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addition of post 62 to the template permits a surgeon to straddle the dura and place post 62 to further assist in the alignment of any further trephining procedures.

Referring now to Fig. 10, template body 48 includes six indentations 50 along the perimeter of the device. The perimeter of the device matches the amount of exposure required for placement of a pair of implants. Preferably, the body is sized to match the space needed to place two cylindrical bone dowels. Therefore, if in placing template body 48, bony structures are encountered which extend into the area needed for implant placement, notches 68, 70, 72, and similar notches on the other portion of the template permit marking of the interfering structure and ultimately passage of a working channel for placement of interbody fusion devices.

Figs. 6 and 7 illustrate still a further embodiment of an intraoperative template according to the present invention. Intraoperative template 80 includes a shaft 82 and an enlarged end 84 similar to the enlarged end 18 previously described on shaft 14 of the retractor mechanism disclosed in Fig. 1. As such, handle 98 is identical to handle 12 and may be pivotally positioned on shaft 82. Intraoperative template 80 includes a template body 86, a guiding tube 88, and an aperture 94 extending through template body 86. As shown in Fig. 6, a removable post 92 with attached handle 90 has been placed in opening 94 to drop into a first trephine hole or to penetrate the disc annulus to stabilize the template during trephining of a first hole through guide tube 88. It will be understood that post 92 and handle 90 may be removed for unilateral templating if desired.

Referring now to Fig. 7, there is shown the intraoperative template of Fig. 6 with interconnected handle 98 joined by connection mechanism 100 as previously described with respect to the retractor mechanism of Fig. 1. A trephine 96 is further disclosed extending through guide tube 88.

In Fig. 8 there is illustrated a further embodiment of a template according to the present invention. Template 116 has a template body and guide tube as previously described with respect to Fig. 6. In this embodiment, shaft 117 includes an offset portion 118 laterally offsetting enlarged head 119 from the lower portion of the shaft.

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It will be understood that this limits the amount of instrumentation within the surgical field and permits greater access.

Referring now to Fig. 9, there is shown yet a further embodiment of an intraoperative template according to another aspect of the present invention.

- 5 Intraoperative template 101 includes a connection mechanism 104 on shaft 102, a template body 106, guiding tube 108, and a post 110. In contrast to the previous embodiments, post 110 includes a substantially straight portion 112 in substantial alignment with the connection 113 of post 110 to template body 106. Between straight section 112 and connection 113, is a laterally extending curved portion 114.
- 10 It will be understood that the curvature of rod 112 away from tube 108 provides still further space for disposing the dura 116 between tube 108 and post 110 during the templating procedure. Post 110 may be removably secured to body 106. Moreover, post 110 is illustrated having a particular curve, it being understood that the locator extension may take an alternative configuration and remain within the scope of the
- 15 present invention.

- Referring now to Fig. 11, there is shown a distractor according to another aspect of the present invention. Distractor 130 includes a shaft 131 with a Hudson-type connection 132 and markings 134 indicating the distraction height created in the disc space by the distraction tip 136. Disposed adjacent indicators 134 is a substantially
- 20 uniform diameter guiding portion 144. Extending further towards distraction tip 136 is a continuously tapering portion 142. Disposed adjacent distractor tip 136 is a further set of indicators 138, again indicating the height of distraction in the disc space created by the orientation of tip 136. Disposed within tapering section 142 is a visualization window 140 extending entirely through shaft 131 permitting
- 25 visualization of structures and vessels on the opposite side of the shaft. The distractor tip of Fig. 11 is a two-position distractor having an insertion position with a first working distraction height. If the first working distraction height is insufficient or a greater distraction is desired, the shaft may be rotated 90° to a second greater working distraction height.

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Referring to Figs. 12 through 14, there is disclosed a modular distraction assembly 150 permitting interchangeability of distraction tips, as well as the ability to leave the distraction tip disposed within the disc space while removing the insertion tool. Referring more specifically to Fig. 12(a), the modular distraction assembly 150 includes a T-handle 180 with a conventional Hudson-type connection mechanism 181 disposed therein. The assembly further includes an inner shaft 152 having an enlarged end 154 adapted for engagement with Hudson mechanism 181 and an opposite threaded end 156. Inner shaft 152 may be disposed within outer tube 160. Outer tube 160 includes a slot driver 162 and an opposite end driving extension 164 having flats 166 for engagement with the T-handle 180 to transmit rotational force to outer tube 160. Preferably, outer tube includes a visualization window 168 extending therethrough. Distractor tip 176 has an internal channel 179 defining internal threads 177 for engagement with threaded end 156 of inner shaft 152 and a slot 178 for engagement with the slot driver of outer tube 160 (see Fig. 14(c)).

Referring now to Figs. 14(a) through (c), there is shown a cross-section of the assembled modular distraction assembly 150. As shown in Fig. 14(b), enlarged end 155 of inner shaft 152 is advanced past balls 186 such that the balls are adjacent a smaller outer diameter 157 of the inner shaft 152. Collar 184 is then advanced towards outer tube 160 such that inclined surfaces 188 extend below balls 186 and reduced internal diameter portion 190 is disposed adjacent balls 186 to forcibly urge balls 186 against reduced outer diameter 157 of shaft 152. It will be understood that the engagement of balls with inner shaft 152 securely holds the inner shaft in position. Handle 180 includes a shaft portion 181 having a configuration adapted to engage the driving flats of extension 164. It will be understood that with collar 184 substantially advanced towards shoulder 165, the inner shaft and outer tube are substantially engaged with handle 180. To complete the engagement in a preferred embodiment, inner shaft 152 must be threadedly engaged with distraction tip 176 prior to attachment of T-handle such that the distal end 171 of outer tube 160 engages the enlarged head 173 of distraction tip 176 to secure the outer tube 160 in engagement with handle 180. It will be understood that to disengage the assembly, collar 184

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must be pulled toward handle 180 until balls 186 are adjacent inclined surfaces 188 and allowed to move away from inner shaft 152. In this position, handle 180 may be displaced longitudinally away from outer tube 160 and removed. Once handle 180 has been removed, inner shaft 152 may be rotated to threadedly disengage from
5 distractor tip 176, thereby allowing the inner shaft and outer tube 160 to be disengaged from distractor tip 176. Inner shaft 152 is preferably retained within outer tube 160 by threads 161. Threads 161 are larger than the internal diameter of threaded opening 163. For complete removal, threads 161 may be threadedly passed through threaded opening 163.

10 Referring now to Fig. 15 and 16, there is shown an outer sleeve in accordance with another aspect of the present invention. Outer sleeve 210 includes a distractor portion 212 having a tip 216 and tapering portion 214 extending back to an area of grooves 218 adapted to engage adjacent bony structures. An opposing distractor portion 213 is similarly formed. The bone engaging portion further includes spikes
15 220 and 221 adapted to be driven into bony structures adjacent the disc space. Outer sleeve 210 further includes visualization windows 222 and 224. Window 222 extends to extended side wall 226. In contrast, window 224 extends closer to the engagement end and terminates adjacent side wall 228. It can be seen that side wall 226 is substantially longer than side wall 228 along longitudinal axis 211. As shown in Fig.
20 15, the longer portion of side wall 226 is provided to engage and protect nerve roots exiting the spinal cord adjacent the surgical site. In contrast, shortened wall 28 provides greater visualization through window 224. Additionally, outer tube 210 includes a markings visualization window 232 for visualizing markings on instruments in the tube indicating the depth of instrument penetration into the disc
25 space.

Referring now to Fig. 17, there is shown a combination of the distractor assembly 150 having a distractor tip 176 in combination with outer sleeve 210. Window 224 permits visualization of the distractor assembly while window 232 permits visualization of markings along the distractor assembly shaft indicating the
30 depth of penetration of the distractor and/or outer sleeve. It will be understood that in

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a typical procedure, distraction assembly 150 is placed prior to the insertion and placement of outer sleeve 210.

Referring now to Figs. 18 through 20, there is disclosed a depth stop mechanism preferably cooperable with the shaft of a tool and an outer sleeve as disclosed herein.

- 5 Such tools can include, without limitation, the reamer and the tap. Depth stop 300 includes an enlarged circumferential abutment shoulder 310 adapted to engage the proximal end of an outer working sleeve to prevent further advancement of the stop and any interconnected shaft. Stop 300 further includes viewing windows 308 to permit visualization of depth markings on a shaft extending within the stop. Stop 300
- 10 includes a manually operated collar 302 which may be axially displaced along axis 301 in the direction of arrow 305 to allow flexing of fingers 306. Collar 302 is normally urged into an extended position by spring 316. Referring specifically to Fig. 19(c), fingers 306 include projections 304 extending internally. The internal projections 304 are configured for engagement within grooves defined along a tool
- 15 shaft of a working tool. Additionally, each finger includes an external taper portion 312 adapted for engagement with bearing surface 314 of collar 302. It will be understood that with collar 302 in a retracted position, bearing surface 314 of collar 302 will be substantially disengaged from taper 312 and thereby permits fingers 306 to disengage from the groove of a tool shaft. With collar 302 in the extended position
- 20 shown in Fig. 19(c), bearing surfaces 314 bear against the tapered surface 312 of each finger to urge projections 304 into a groove of a tool shaft. In this manner, a user may quickly and easily disengage the locking mechanism of the stop to advance or retract a tool shaft and then re-engage the stop at the desired position. However, engagement with the tool shaft is indexed by the spacing of grooves on the shaft so the exact
- 25 location of the stop may be easily known. The tool shaft may be rotated with respect to the stop mechanism to display the appropriate depth numeral indicated on the shaft in window 308. Preferably, collar 302 will extend at least partially beyond fingers 306 to limit the possibility that surgical staff may snag protective apparel on exposed fingers 306.

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In a first embodiment shown in Fig. 19(a), collar 302 is retained on housing 306 by retaining pin 322 extending into the housing and through a slot 320. Retaining pin 322 prevents rotation of collar 232 with respect to housing 318. In an alternate embodiment shown in Figs. 24, collar 302 defines an L-shaped slot 324 which permits axial displacement of collar 302 with respect to body 318, as well as a slight amount of rotation within the slot. It will be understood that the L-shaped slot 324 permits the depth stop mechanism to be locked in a disengaged position which permits free movement of a tool shaft through the depth stop. This is a desirable construction in some instances for easy removal of the depth stop from the tool shaft, as well as for utilization of the tool without the constraints of a depth stop mechanism.

Referring now to Fig. 21, there is shown an outer sleeve 210 in combination with a depth stop 300 and reamer 351. The reamer 351 is interconnected with a T-handle 180 having Hudson connection engaged with the reamer shaft. It will be understood that depth stop 300 has been positioned to engage the upper portion of outer sleeve 210 to prevent further advancement of the reamer beyond the set depth.

Referring now to Fig. 22, there is shown a depth gauge according to a further aspect of the present invention. Depth gauge 360 includes an upper portion 362 having a plurality of markings 366 indicating the depth of the distal portion of the gauge into the vertebral bodies. Lower portion 364 is sized to substantially match the outer diameter of a cylindrical dowel to be inserted into an opening formed between adjacent vertebra. It will be understood that close matching of the outer diameter of depth gauge 360 with the desired diameter of the dowel to be placed, will insure that the opening formed between the vertebral bodies in the disc space is substantially clear of debris and closely matches the outer diameter of the dowel to be placed. Previously, there has been a possibility that debris could block a portion of the opening despite the fact that a depth gauge of a smaller diameter may reach the farthest reaches of the opening. In such a situation, advancement of a dowel, particularly in the case of a more brittle bone dowel, may be impeded by the debris left in the opening, resulting in the possibility of damage to the dowel and/or the opening when excessive force is applied to advance the dowel. In a further aspect of

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the present invention, portion 364 is radiolucent and includes a number of markers to identify the location of the depth gauge by radiographic means. Radiomarker 372 indicates the most distal position of the depth gauge and subsequent position of the implant. Radiographic markings 370 and 376 indicate the proximal ends of various sizes of implants. The distance 378 between 372 and 370 is approximately 20mm, a conventional implant size, while the distance between 372 and line 376 is approximately 26mm, a further conventional implant length.

Referring now to Fig. 23, there is shown the depth gauge of Fig. 22 inserted into and extending beyond outer sleeve 210. The depth of extension beyond outer sleeve 210 of depth gauge 360 is shown by the numeral in window 232 in the outer sleeve.

Fig. 24 illustrates a tap 390 interconnected with the shaft and handle 180 extending through outer sleeve 210. It will be understood that markings on the shaft of the tap may be displayed in window 232 to indicate the length of extension beyond the outer tube. Additionally, the assembly includes an adjustable depth stop 300 which engages the proximal portion of outer sleeve 210 to prevent over-advancement of tap head 390 into the disc space.

Referring now to Fig. 25, there is shown an implant insertion device 400 according to the present invention. The implant insertion device includes depth markings along the shaft of the device. Depth markings 406 indicate when the dowel is first engaged in the disc space. In the past, it was possible that when one relied only upon feel, the dowel could engage obstructions within the working channel of the outer sleeve or other type of inserting device, giving the false impression that the implant 402 was engaging the disc space and potentially leading to damage to the implant as it was forced against the obstruction. With the markings 406, multiple markings for different implant lengths, the user can visually verify whether the implant has engaged the disc space. Markings 404 are provided to indicate the depth the implant has been inserted into the disc space.

In use, an initial incision provides the approach and exposure of the posterior spinal surgical site. Exposure of the dura is accomplished in a customary fashion. In one aspect of the method according to the present invention, a retractor according to

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the present invention is used to retract the dura. Once retracted, the pivotal handle of the retractor is pivoted out of the way to permit an assistant to hold the retractor without interfering in the operating field.

A template in accordance with the present invention may then be placed to
5 extend on both sides of the dura simultaneously with a guide tube positioned on one side and a locator extension positioned on the opposite side. A trephine is then passed through the guide tube and into the disc space to remove a portion of the disc and adjacent tissue. The template may be removed and repositioned to again straddle the dura with the locator extension in the previously trephined hole and the guide
10 positioned on the opposite side of the dura. Again, the trephine is passed through the guide tube and into the disc space to form an opening therein. With the template remaining in position across the dura, the surrounding bone structures are evaluated for removal to permit placement of a guide sleeve. If bone elements, facet or lamina, are positioned beneath the template body, a marking device such as a cauterizer is
15 used to mark the offending structure in one of the notches provided. After the bone structures have been marked, the template is removed and the bone removed in a conventional manner. Preferably, the template is repositioned to straddle the dura and the field is again checked to verify that a guide tube may be placed without obstruction. If not, further bone marking and removal is conducted. Once the space
20 is prepared for guide tube placement, the template is removed.

In accordance with another aspect of the invention, a distractor is inserted into the disc space in one of the previously trephine openings. In a similar manner, a second distractor is inserted into the second trephined opening. If necessary, a distractor having two working heights is inserted in a first smaller height and rotated
25 90 degrees after insertion to a second larger height. Moreover, a tip having the desired configuration may be selected and mounted on the modular distraction assembly 150 prior to insertion. In some instances, the tip may be disconnected from the distractor assembly and temporarily left in the disc space.

The further description of the method will be described with respect to
30 placement of single dowel, it being understood that the steps may be repeated on the

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opposite side to implant a second implant. A guide tube is positioned over the distractor and advanced until the distracting flanges are positioned in the disc space. It will be understood that the enlarged portion on the distractor shaft guides the guide tube into a concentric position about the distractor. Once the guide tube is securely
5 seated, the distractor may be withdrawn. The disc space will then be prepared to receive an implant having a preselected length and diameter. A reamer of the appropriate diameter is selected and a depth stop according to the present invention is positioned on the shaft at the preselected depth markings. The reamer is rotatably advanced into the disc space until the depth stop engages the guide tube to limit
10 further advancement. Preferably, a depth gauge according to the present invention is inserted to verify complete reaming to the preselected depth and removal of debris. If a threaded implant will be used, a depth stop will be positioned on a tap shaft at the preselected depth. The tap is rotatably inserted into the disc space until the depth stop engages the guide tube. The tap is removed and the depth gauge may be reinserted to
15 verify that the proper sized opening has been formed and is substantially unobstructed. At this point an implant is inserted using the implant inserter. Once the implant is inserted, the guide tube may be withdrawn and the procedure repeated on the opposite side.

While the invention has been illustrated and described in detail in the drawings
20 and foregoing description, the same is to be considered as illustrative and not restrictive in character, it being understood that only the preferred embodiments have been shown and described and that all changes and modifications that come within the spirit of the invention are desired to be protected.

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What is claimed is:

1. A retractor, comprising:
a retractor blade;
5 a shaft having a first portion and an opposite second portion, said first portion connected to said retractor blade;
a handle pivotally mounted on said second portion; and
a locking mechanism selectively locking said handle to said second portion to limit pivotal movement of said handle in relation to said shaft.
10
2. The retractor of claim 1, wherein said locking mechanism includes said second end having a plurality of grooves and said handle includes a projecting portion selectively engageable with at least one of said grooves.
- 15 3. The retractor of claim 1, wherein said handle is removably mounted on said second portion.
4. The retractor of claim 1, wherein said locking mechanism locks into a plurality of preset positions.
20
5. The retractor of claim 4, wherein said locking mechanism includes at least four preset positions.
6. The retractor of claim 4, wherein said locking mechanism includes
25 eight preset positions.
7. The retractor of claim 1, wherein said shaft includes a first longitudinal axis and said handle includes a second longitudinal axis, said second axis intersecting said first axis at approximately a 45 degree angle.
30

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8. The retractor of claim 2, wherein said locking mechanism includes a mechanism to bias the locking mechanism to a locked position.

9. The retractor of claim 3, wherein said handle includes a chamber for
5 receiving said second portion, said chamber having an opening for passage of said second portion and a locking arm moveable between a locked position, an adjustment position, and a released position, said locked position limiting pivotal movement of said handle in relation to said shaft, said adjustment position
10 permitting pivotal movement of said handle in relation to said shaft but preventing removal of said handle from said shaft, and said released position permitting removal of said handle from said shaft.

10. A method of dura retraction for posterior access in the spine, the method comprising:
15 providing a retractor having a retractor blade pivotally connected to a handle with a locking mechanism to selectively lock the handle to the retractor;
exposing a portion of the dura;
inserting the retractor with the handle in an insertion position and the locking mechanism in a locked position;
20 retracting the dura to expose underlying spinal elements;
unlocking the locking mechanism to allow the handle to pivot in relation to the retractor blade;
pivoting the handle to a holding position; and
locking the locking mechanism to maintain the handle in the locked
25 position.

11. A template for straddling the dura in a spinal surgery to facilitate marking a surgical site, said template comprising:
a body portion having an upper surface and a lower surface, and an opening
30 formed between said upper surface and said lower surface;

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a shaft having a first end and a second end, said first end connected to said upper surface;

a working tube positioned in substantial alignment with said opening and extending from said lower surface, said tube having a first diameter; and

5 a locator extension engaged with said body, said locator extension extending from said lower surface and spaced from said working tube to provide a space for the dura, said locator extension have a second diameter that is less than said first diameter.

10 12. The template of claim 11, wherein said locator extension is removably engaged with said body.

13. The template of claim 11, wherein said body is sized to approximate a maximum area of an instrument set, and said body includes a perimeter with a
15 plurality of notches for marking tissue that must be removed to accommodate the instrument set.

14. The template of claim 11, further including a handle pivotally connected to said second end and a locking mechanism controllable to selectively
20 limit pivotal movement between said shaft and said handle.

15. The template of claim 11, wherein said locator extension is solid.

16. The template of claim 11, wherein said working tube is integral
25 with said body.

17. The template of claim 11, wherein said locator extension includes a connection end connected to said body, an opposite engagement end and a curved portion between said connection end and said engagement end.

30

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18. The template of claim 11, wherein said shaft includes an offset segment between said first end and said second end.

19. The template of claim 13, wherein said body includes two inter-
5 connected semi-circular lobes defining the maximum area of an instrument set.

20. A spinal disc space distractor assembly, the assembly comprising:
an outer shaft having a first end and an opposite second end, said shaft
including a first driving shoulder adjacent said first end for transmitting rotational
10 force and an opposite second driving shoulder adjacent said second end for
receiving a rotational force;

an inner shaft slidably disposed within at least a portion of said outer shaft,
said inner shaft having a first connection end and an opposite second connection
end, said first connection end disposed adjacent said first end;

15 a distraction tip, said tip having a driving surface adapted for engagement
with said first driving shoulder and a connection surface adapted for engagement
with said first connection end; and

a handle having a connection mechanism selectively engagable with said
second connection end and a handle driving surface adapted for engagement with
20 said second driving shoulder to transmit rotational force;

wherein with said inner shaft connected to said tip, connection of said
connection mechanism with said inner shaft second connection end maintains said
first driving end in engagement with said driving surface and said second driving
end in engagement with said second driving surface.

25

21. The distractor of claim 20, wherein said outer shaft includes a
tapered portion between said first end and said second end.

22. The distractor of claim 21, wherein said first end has a smaller
30 diameter than said second end.

-25-

23. The distractor of claim 20, wherein said outer shaft includes a longitudinal axis and defines a window extending through said shaft transverse to said longitudinal axis.

5 24. The distractor of claim 20, wherein said inner shaft is captured within said outer shaft to limit movement between said outer shaft and said inner shaft.

 25. A spinal disc space distractor, comprising:
10 a distractor tip; and
 a shaft having a first end connected to said distractor tip, an opposite second end and a tapering portion disposed between said first end and said second end, said tapering portion tapering from a larger configuration proximal said second end to a smaller configuration proximal said first end.

15 26. The distractor of claim 25, wherein said shaft includes a longitudinal axis and defines a window extending through said shaft transverse to said longitudinal axis.

20 27. The distractor of claim 25, wherein said distractor tip is removably connected to said shaft.

 28. The distractor of claim 27, further including an inner shaft disposed within said outer shaft, said inner shaft adapted to engage said distractor tip.

25 29. A spinal disc space distractor, comprising:
 a shaft having a first end and an opposite second end with a longitudinal axis extending between said first end and said second end;
 a distractor tip disposed adjacent said first end; and
30 said shaft defining a window extending transverse to said longitudinal axis.

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30. An instrument for determining correct formation of an opening between two adjacent vertebra, said instrument comprising:

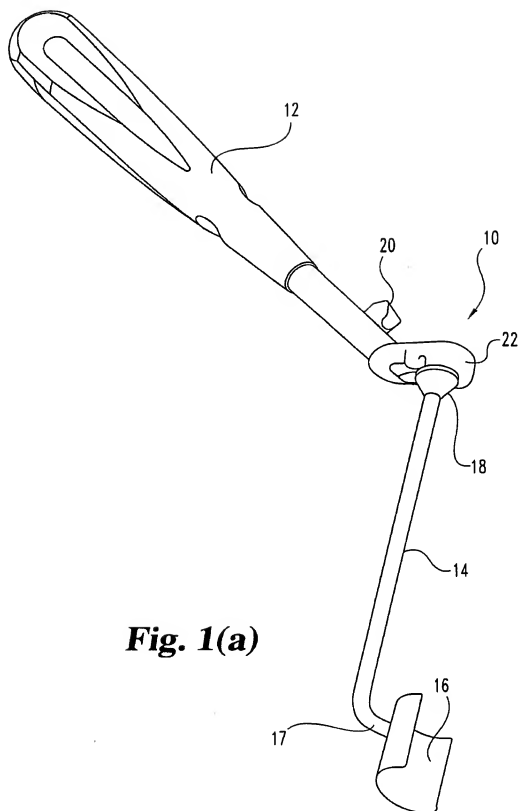
a shaft;

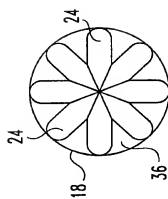
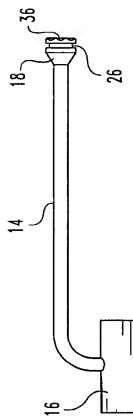
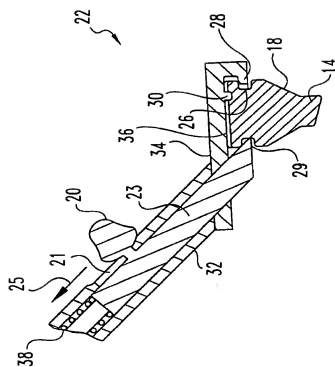
5 a probe having the dimensions of an opening to receiving an implant, said probe attached to said shaft.

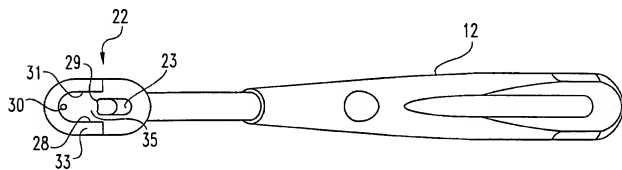
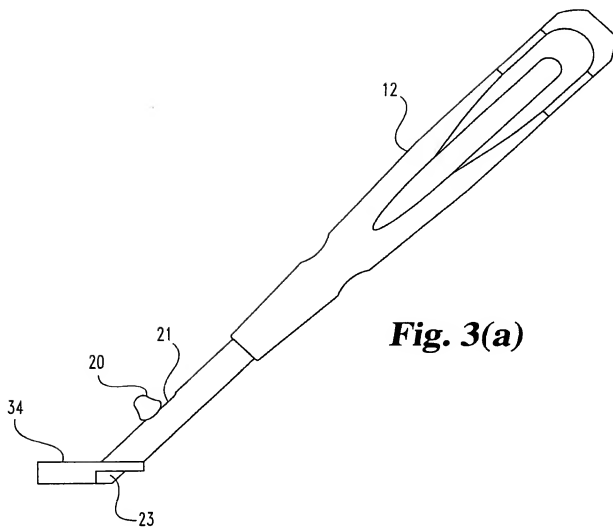
31. An instrument for evaluating the depth of an opening between two adjacent vertebral bodies, comprising:

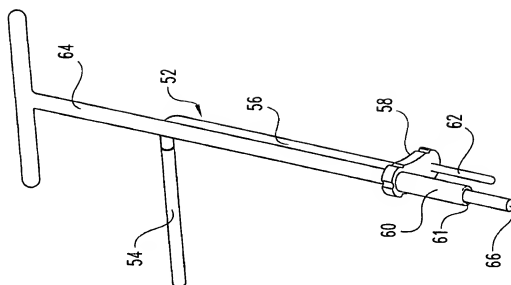
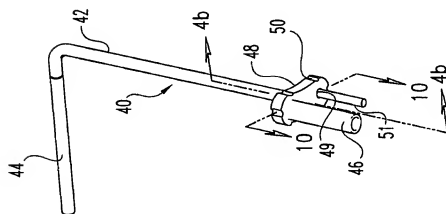
10 an elongated shaft;

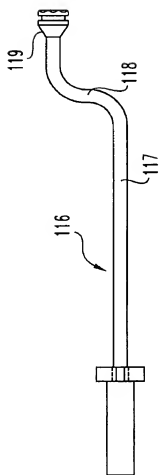
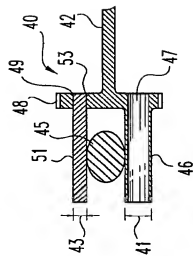
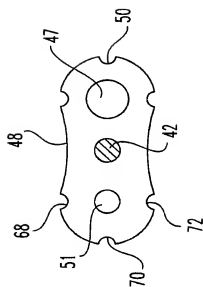
a radiolucent tip attached to said shaft, said tip including at least one radiopaque marker.

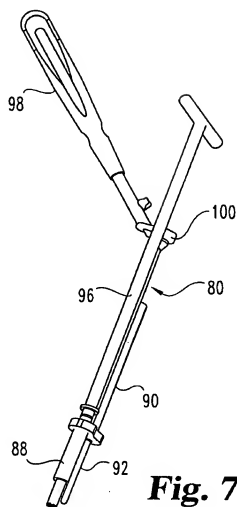
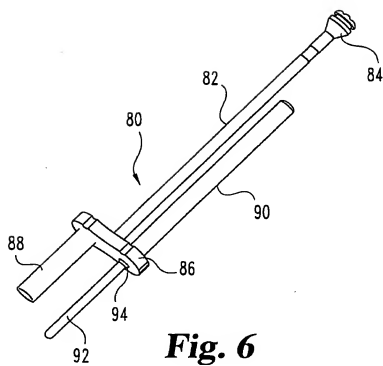
**Fig. 1(a)**

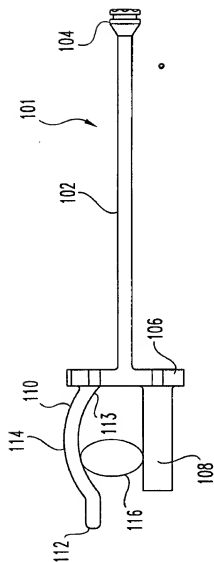
**Fig. 2(a)****Fig. 2(b)****Fig. 1(b)**

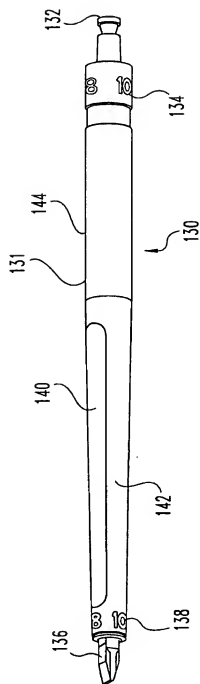


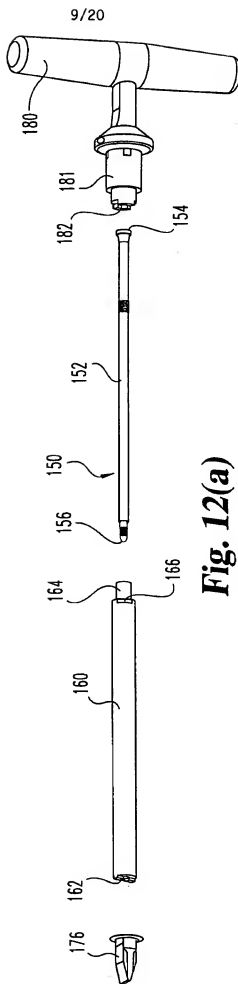
**Fig. 5****Fig. 4(a)**

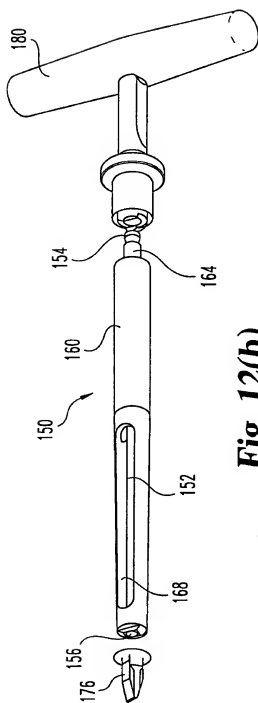
**Fig. 8****Fig. 4(b)****Fig. 10**

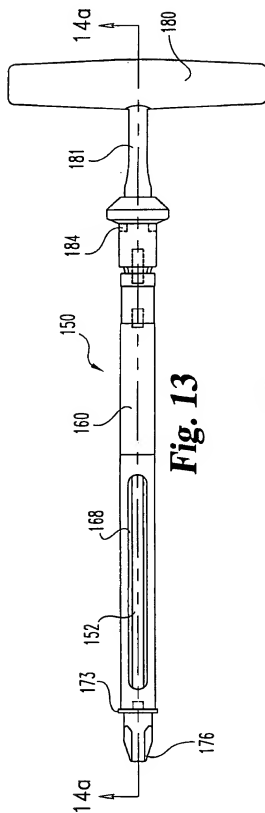
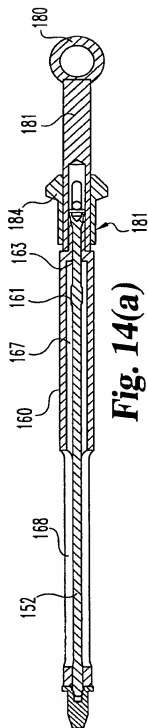
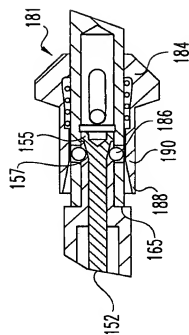
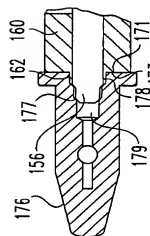


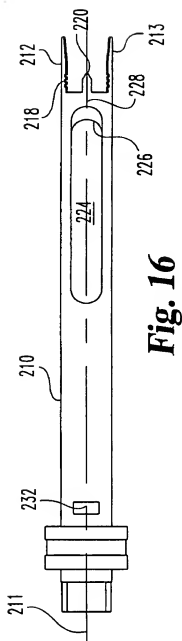
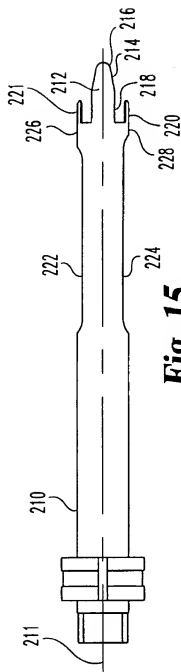
**Fig. 9**

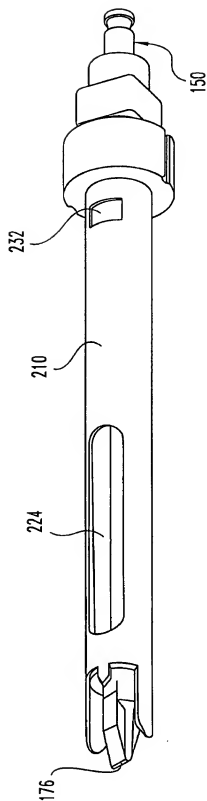
**Fig. 11**

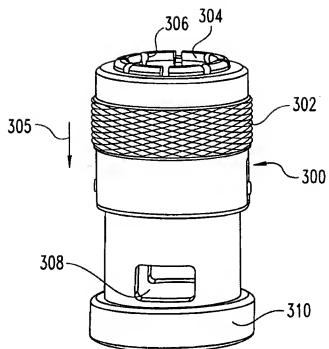
**Fig. 12(a)**

**Fig. 12(b)**

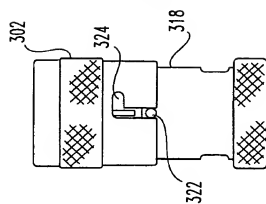
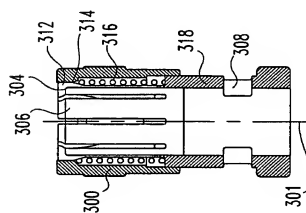
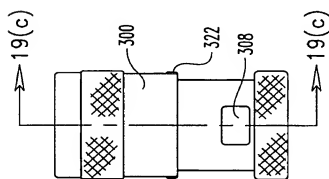
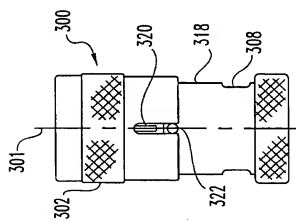
**Fig. 13****Fig. 14(a)****Fig. 14(b)****Fig. 14(c)**

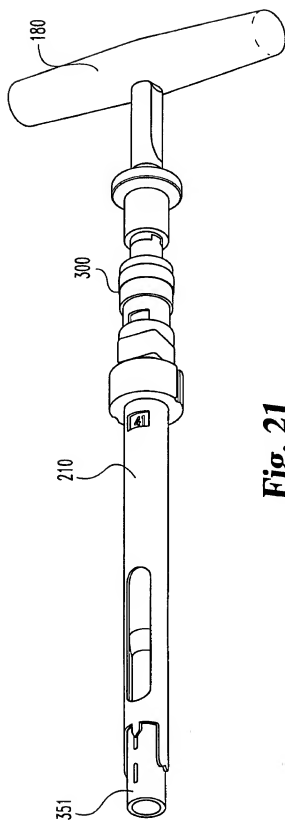


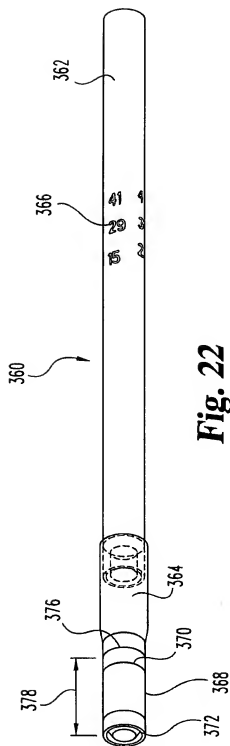
**Fig. 17**

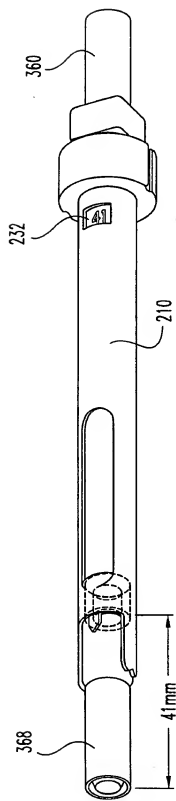
**Fig. 18**

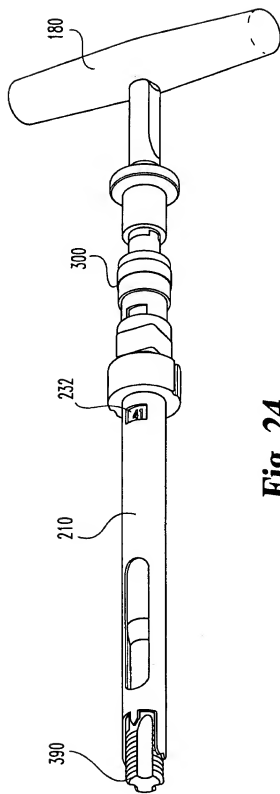
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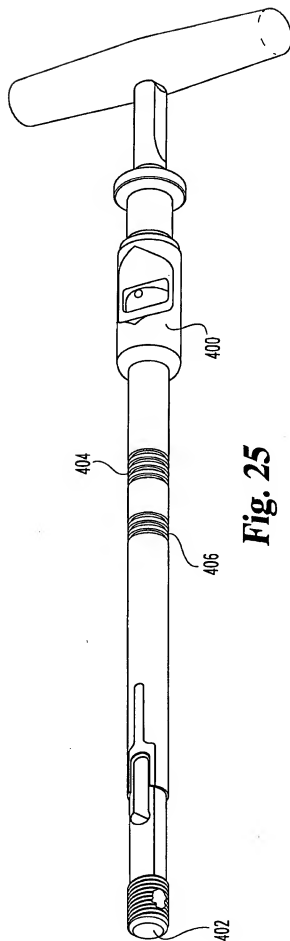
**Fig. 20****Fig. 19(c)****Fig. 19(b)****Fig. 19(a)**

**Fig. 21**



**Fig. 23**

**Fig. 24**

**Fig. 25**



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(57) Abstract			
<p>A method and instrumentation for spinal interbody fusion is disclosed. The instruments and methods are particularly adapted for interbody fusion from a posterior approach to the spine. One instrument is a retractor (10) having a lockable pivotally mounted handle (12). Another instrument is a template (100) for straddling the dura. A modular distractor (150) is also provided and preferably includes a tapered shaft (160) with a visualization window (168) disposed therein. Yet another instrument is a depth gauge (360) to verify bone opening depth and dimension, preferably including a radiopaque portion (370). A method contemplates the use of these instruments to prepare a disc space to receive an implant.</p>			

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CZ	Czech Republic	LC	Saint Lucia	RU	Russian Federation		
DE	Germany	LI	Liechtenstein	SD	Sudan		
DK	Denmark	LK	Sri Lanka	SE	Sweden		
EE	Estonia	LR	Liberia	SG	Singapore		

Internat'l Application No
PCT/US 99/07805

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4 934 352 A (E.M.SULLIVAN) 19 June 1990 (1990-06-19)	1,3,7
A	column 3, line 32 - column 4, line 10; figures 1-3 ---	2,4-6,8, 9
X	US 5 379 758 A (S.J.SNYDER) 10 January 1995 (1995-01-10)	1,3
A	column 4, line 41 - line 58; figure 4 ---	
A	US 1 708 578 A (T.F.HYDE) 9 April 1929 (1929-04-09)	1,3
	page 1, line 58 - line 60 page 1, line 70 - line 73; figures 1,5 ---	
A	US 5 558 621 A (T.L.HEIL) 24 September 1996 (1996-09-24)	7
	figure 1 ---	
	--- -/--	

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

^a Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

E earlier document but published on or after the international filing date

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"O" document referring to an oral disclosure, use, exhibition or other means

P document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

A document member of the same patent family

Date of the actual completion of the international search:

27 October 1999

Date of mailing of the International search report

8 November 1999

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INTERNATIONAL SEARCH REPORT

Internat'l Application No
PCT/US 99/07805

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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A	US 5 055 104 A (C.D.RAY) 8 October 1991 (1991-10-08) column 5, line 64 -column 6, line 4; figures 8,9 ---	11
A	US 5 645 549 A (L.M.BOYD AND E.RAY) 8 July 1997 (1997-07-08) abstract; figure 14 ---	11
X	US 5 697 889 A (G.J.SLOTMAN ET.AL) 16 December 1997 (1997-12-16) figures 1,2,6 ---	25,27,28
X	EP 0 796 593 A (SURGICAL DYNAMICS) 24 September 1997 (1997-09-24) column 6, line 42 -column 7, line 37; figure 1 ---	29
A	WO 96 27345 A (G.K.MICHELSON) 12 September 1996 (1996-09-12) page 50, line 1 -page 51, line 7; figure 2 ---	20,24
A	US 5 015 247 A (G.K.MICHELSON) 14 May 1991 (1991-05-14) column 8, line 57 -column 9, line 6 column 10, line 15 - line 17; figure 4C ---	20,22
X	WO 95 21590 A (NOBELPHARMA) 17 August 1995 (1995-08-17) page 6, line 36 -page 7, line 5; figure 4 ---	30
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A	WO 92 20294 A (S.M.F.EISENSTEIN AND J.K.MIDDLETON) 26 November 1992 (1992-11-26) page 15, line 17 - line 21; figure 9 ---	30
A	US 5 361 766 A (D.NICHOLS AND D.SZALAY) 8 November 1994 (1994-11-08) column 2, line 21 - line 53 column 3, line 29 - line 45 -----	31

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 99/07805**Box I Observations where certain claims were found unsearchable (Continuation of Item 1 of first sheet)**

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 10
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(e).

Box II Observations where unity of invention is lacking (Continuation of Item 2 of first sheet)

This International Searching Authority found multiple inventions in this International application, as follows:

see additional sheet

1. ☒ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☒ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International Application No. PCT/US 99/07805

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-9

Retractor

2. Claims: 11-19

Template for marking a surgical site

3. Claims: 20-29

Spinal disc space distractors

4. Claims: 30-31

Instruments for determining correct formation of a vertebral opening

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US 99/07805

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INTERNATIONAL SEARCH REPORT

Information on patent family members

Inter. Appl. No.

PCT/US 99/07805

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